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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/780,748	02/09/2001	Henry Lamparski	260/058	6949

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EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT PAPER NUMBER

1644

DATE MAILED: 01/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/780,748

Applicant(s)

LAMPARSKI ET AL.

Examiner

DiBrino Marianne

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/25/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 6-9, 11-23, 35 and 36, drawn to a method of preparing a immunogenic membrane vesicle and pharmaceutical composition thereof, said method comprising contacting the said vesicle with a peptide, classified in Class 424, subclass 325.

II. Claim 10, 35 and 36, drawn to a method of preparing a immunogenic membrane vesicle and pharmaceutical composition thereof, said method comprising contacting the said vesicle with a lipid, classified in Class 424, subclass 355.

III. Claims 29-34, drawn to a pharmaceutical composition comprising an immunogenic membrane vesicle loaded with an immunogenic peptide, and further comprising a pharmaceutically acceptable diluent or carrier, classified in Class 424, subclass 193.1.

IV. Claims 29-31, drawn to a pharmaceutical composition comprising an immunogenic membrane vesicle loaded with an immunogenic lipid, and further comprising a pharmaceutically acceptable diluent or carrier, classified in Class 424, subclass 190.1.

V. Claim 27, drawn to a method of producing an immune response in a subject, said method comprising obtaining a biological sample comprised of dendritic cells, isolating or purifying a membrane vesicle from said biological sample, contacting a membrane vesicle with a peptide to bind an MHC molecule at the surface of the said membrane vesicle, and administering the membrane vesicle to a subject to produce an immune response, classified in Class 435, subclass 372.2 and Class 424, subclass 193.1, respectively.

VI. Claim 28, drawn to a method of producing an immune response in a subject, said method comprising obtaining a biological sample comprised of dendritic cells, isolating or purifying a membrane vesicle from said biological sample, contacting a membrane vesicle with a lipid to bind a CD1 molecule at the surface of the said membrane vesicle, and administering the membrane vesicle to a subject to produce an immune response, classified in Class 435, subclass 372.1, and Class 424, subclass 190.1, respectively.

Art Unit: 1644

2. Claims 1-5 link inventions I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 1-5. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

3. Claims 24-26 link inventions V and VI. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claims, claims 24-26. Upon the allowance of the linking claim, the restriction requirement as to the linked inventions shall be withdrawn and any claim depending from or otherwise including all the limitations of the allowable linking claim will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim depending from or including all the limitations of the allowable linking claim is presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March

Art Unit: 1644

26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

5. Inventions I, II, V and VI are different methods.

These inventions require different ingredients and process steps to accomplish preparing an immunogenic MHC/peptide membrane vesicle and composition thereof (Group I), or preparing an immunogenic CD1/lipid membrane vesicle and composition thereof (Group II), or producing an immune response in a subject using an immunogenic MHC/peptide membrane vesicle (Group V), or producing an immune response in a subject using an immunogenic CD1/lipid membrane vesicle (Group VI). For example, the immunogenic membrane vesicles made in Group I or used in the method of Group V comprise MHC/peptide complexes that have different structures and produce differently restricted T cell responses than do the immunogenic membrane vesicles made in Group II or used in method of Group VI.

6. Inventions III and IV are different products.

Membrane vesicles comprising MHC/peptide complexes and membrane vesicles comprising CD1/lipid complexes are distinct because their structures and modes of action are different in that they induce differently restricted immune responses.

7. Inventions I and III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. 806.05(f)).

In the instant case, the product as claimed can be made by contacting a live cell with peptide, then isolating or purifying the membrane vesicle.

8. Inventions II and IV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (M.P.E.P. 806.05(f)).

In the instant case, the product as claimed can be made by contacting a live cell with a lipid, then isolating or purifying the membrane vesicle.

Art Unit: 1644

9. Inventions III and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P., 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

10. Inventions IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P., 806.05(h)).

In the instant case, the product as claimed can be used in a materially different process such as immunopurification procedures or detection assays.

Therefore they are patentably distinct.

11. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-VI is not required for any other group from Groups I-VI and Groups I-VI have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

12. **If Applicant elects the Invention of Group I**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (**a specific peptide**, for example, a class I-restricted peptide, **or a class II-restricted peptide, or a peptide eluate of tumor cells, and specific biological sample**, for example, one comprising human dendritic cells, **and specific method steps**) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

13. **If Applicant elects the Invention of Group II**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (**a specific lipid**, for example, a microbial lipid, **and specific biological sample**, for example, one comprising human dendritic cells, **and specific method steps**) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

Art Unit: 1644

14. **If Applicant elects the Invention of Group III**, Applicant is further required to (1) elect a single disclosed species (**a specific peptide**, for example, a class I-restricted peptide, **or** a class II-restricted peptide, **and a specific APC**, for example, dendritic cells, **and a specific % of HLA molecule occupancy with exogenously added peptide**, for example, at least 15%) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

15. **If Applicant elects the Invention of Group IV**, Applicant is further required to (1) elect a single disclosed species (**a specific lipid**, for example, a microbial lipid, **and a specific APC**, for example, dendritic cells) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

16. **If Applicant elects the Invention of Group V**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (**a specific peptide**, for example, a class I-restricted peptide, **or** a class II-restricted peptide, **and a specific biological sample**, for example, autologous dendritic cells, **and specific method steps**) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

17. **If Applicant elects the Invention of Group VI**, Applicant is further required to (1) elect a single disclosed species to be used in the claimed method (**a specific lipid**, for example, a microbial lipid, **and a specific biological sample**, for example, autologous dendritic cells, **and specific method steps**) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

18. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Art Unit: 1644

19. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

20. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

21. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

22. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

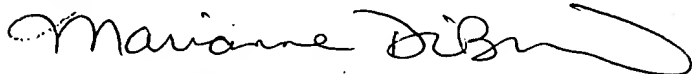
23. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

24. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1644

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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